

REMARKS

Applicant respectfully requests entry of the amendments and reconsideration of the claims.

Rejection under 35 U.S.C. § 103(a)

The Examiner rejects claims 21-25 as allegedly obvious over U.S. Patent Publication No. 2001/0056068 (Chwalisz et al.) in view of White & Campbell (Chapter 17 of Clinical Pharmacy & Therapeutics (Herfindal et al., ed.), p. 307-331, 1992). Applicant respectfully traverses.

As articulated by the Supreme Court, a combination is obvious if it is no more than the predictable use of known elements according to their established functions; and there was a reason to combine the known elements. *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). To make a *prima facie* case of obviousness, “it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.” *Id.* Applicants submit that the Examiner does not make a *prima facie* case of obviousness because the prior art does not suggest the claimed method of claims 21-25.

Applicant respectfully asserts that a person of ordinary skill in the art would not look to the Chwalisz et al. publication for determining predictable use of known elements according to their established functions. In addition, Applicant contends that a person of skill in the art would not combine Chwalisz et al. with any other reputable reference. The Chwalisz et al. publication is merely a “laundry list” of diseases (see *Ex parte McMichael*, Appeal 2009-002709 (BPAI 2009)) that Chwalisz et al. claim to be treatable by citrulline and citrulline derivatives. There is absolutely no data, and the recited diseases cover a large range of diseases—all cardiovascular diseases, respiratory diseases, inflammatory disease, Alzheimer’s disease, growth hormone disorders, behaviour changes, hair loss, preeclampsia, preterm labor, dysmenorrhea, infertility, peri-menopausal syndrome, male impotence, early pregnancy loss, and cervical dystocia. Applicant contends that a person of skill in the art would be rather incredulous at the prospect of this wonder drug treating all of these diseases with such divergent pathologies.

Providing further distrust of the application, Chwalisz et al. characterize diabetes mellitus

as a "gastrointestinal tract disorder" at paragraph 51. Obviously, diabetes mellitus is not a gastrointestinal tract disorder as it results from destruction of the islets of Langerhans in the pancreas. It does not even take ordinary skill in the art to realize that diabetes mellitus is an endocrine disease and not a GI tract disease.

For at least these reasons, the Chwalisz et al. publication has no credibility for one of ordinary skill in the art. Further, one would not be motivated to combine the Chwalisz et al. publication with any credible reference. In view of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a).

Summary

In view of the above amendments and remarks, the applicant respectfully requests a Notice of Allowance. If the Examiner believes a telephone conference would advance prosecution of this application, the Examiner is invited to telephone the undersigned at the below listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

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/Brian R. Dorn/
Brian R. Dorn
Reg. No. 57,395

